



CropLife America

Strategic Oversight Council

October 27, 2020
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Office of Pesticide Programs
U.S. Environmental Protection Agency



Discussion Topics

- FY20 Registration Highlights
- FY20 Registration Review Updates
- COVID-19 Response
- FY20 Rulemakings
- Biotechnology Highlights
- Endangered Species Highlights
- Work Supporting the Pollinator Initiative
- Certification of Pesticide Applicators Rule
- Digital Transformation

EPA FY20 In-Processing

- Over 13,315 submission via Portal
- Over 71,822 documents processed

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Initiated electronic PRIA in-processing- moved away from a hands-on initial data completeness screen and replaced the 21-day room step

EPA FY20 Registration Highlights

- Registered 16 new active ingredients
- Registered 163 new uses of existing pesticides
- Overall, 2,385 PRIA actions completed
 - 98% on-time completion rate
 - 34% renegotiation rate

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Some of the new active ingredients include:

-Cry14Ab1 Soybean Cyst Nematode PIP seed increase registration and related tolerance exemption for a PIP that targets a major agricultural pest.

-Alphachloralose - a novel rodenticide used to control mice inside homes and buildings, and the first new rodenticide active ingredient registered in over 20 years.

-It acts by lowering the body temperature in mice. Mice then experience hypothermia, enter a chemical-induced sleep and die within as little as a few hours.

-NSPW Nanosilver was registered for use in textiles, including fabrics, sportswear, footwear, linens, awnings as a materials preservative.

Significant New Use includes:

Fluopyram: fungicide seed treatment new use was approved for applications to canola to protect against soilborne Blackleg, one of the most important diseases of canola worldwide.

EPA FY20 Registration Highlights

■ 68 Section 18 emergency exemption decisions

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An emergency public health exemption was authorized for use of the first surface coating product, SurfaceWise2, which has a 7-day efficacy claim against coronaviruses, like SARS-CoV-2. The authorization was for use in Texas on American Airlines and in two medical facilities.

An emergency public health exemption was authorized for use of VigorOx 15/23 Antimicrobial Agent to treat regulated medical waste potentially contaminated with SARS-CoV-2

An emergency public health exemption was authorized for use of seven antimicrobial products in healthcare settings to disinfect against candida auris, *C. auris*, which is an emerging human health threat on the U.S. that causes infections with high mortality rates and limited treatment options.

EPA FY20 Registration Highlights

- Worked closely with industry trade organizations in addressing supply chain challenges (including those posed by the pandemic):
 - improving efficiencies in the pesticide registration process by allowing manufacturers to obtain certain inert ingredients (commodity inert ingredients) from different suppliers without checking with the agency for approval
- This effort began with the development of criteria for classifying an inert ingredient as a "commodity inert ingredient" and in the publication of a list of commodity inert ingredients

EPA OPP Gold Seal Letters

- ※ A Gold Seal letter certifies that a pesticide product being exported is legally registered in the U.S. with the EPA
- ※ The Agency process **~400** Gold Seal actions yearly, and registrants can request up to five letters per action
- ※ Due to the COVID-19 public health emergency, the Agency implemented full-time telework
- ※ As a result, providing traditional physical Gold Seal letters with embossed seals became impractical
- ※ To meet the needs of industry, OPP developed a new digital process for Gold Seals whereby, an electronic seal is inserted into the Gold Seal letter, signed electronically, and emailed to registrants
- ※ The EPA is working with the U.S. Department of State help ensure the new electronic gold seal and digitized letters are recognized as "legitimate" EPA documentation for their authentication purposes
- ※ The current launch date for the updated Gold Seal website information is early November.

EPA Registration Review Decisions - Q4

- **Registration Review Decisions**
 - 98 completions in FY20
- **Draft Risk Assessments (DRAs) Completed**
 - 99 DRAs completed

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Significant work done on chemicals with a lot of public attention, including: Atrazine, Chlorpyrifos, Paraquat, DDVP/Naled, Chlorine Gas, TCVP, Pyrethroids, Triazines, Methyl Bromide

EPA Registration Review Highlights

Overall Registration Review Status

- 646 draft risk assessments completed (~11% remaining)
- 551 proposed interim decisions complete (~24% remaining)
- 481 final or interim decisions complete (~34% remaining)

EPA Registration Review Updates

Atrazine

- * In September, EPA released the interim decisions for the triazines (atrazine, propazine and simazine) which finalize measures to protect human health and mitigate potential ecological risks while continuing to provide farmers with the valuable tools to control weeds in crops
- * Specifically, the agency is requiring mitigation measures that:
 - ◊ Reduce the maximum application rate for atrazine and simazine when used on residential turf in order to protect children who crawl or play on atrazine-treated grass;
 - ◊ Add requirement for irrigation immediately after simazine application to residential turf;
 - ◊ Require additional personal protective equipment for workers who apply atrazine and simazine to reduce occupational risks associated with certain uses;
 - ◊ Finalize label requirements for all three triazines to include mandatory spray drift control measures to minimize pesticide drift into non-target areas, including water bodies; and,
 - ◊ Finalize label directions for herbicide resistance to reduce the problem of weeds becoming resistant to atrazine
- * These mitigation measures will go into effect once EPA and states approve the new labels

EPA Registration Review Updates

Chlorpyrifos

- * EPA recently announced in the Federal Register the publication of the ecological and revised human health draft risk assessments.
- * The Proposed Interim Decision for chlorpyrifos is scheduled to be made available to the public in 2020.

Glyphosate

- * In early February 2020, EPA issued the Glyphosate Interim Decision, which included mitigation and label changes to target pesticide sprays on intended pests, protect pollinators, and reduce the problem of weeds becoming resistant to glyphosate.
- * After a thorough review of the best available science, as required under FIFRA, EPA concluded that there are no risks of concern to human health when glyphosate is used in accordance with its current label and that glyphosate is not a carcinogen.
- * EPA's scientific findings on human health risk are consistent with the conclusions of science reviews by many other countries and other federal agencies.

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EPA Registration Review Updates

• **Rodenticides**

- The draft risk assessments for the rodenticides were completed this fiscal year
- The next steps in the registration review process include public comment on the risk assessments, followed by the Proposed Interim Decision in early 2021
- The Interim Decisions for the rodenticides are scheduled for late 2021

• **Pyrethroids**

- Throughout 2020, EPA published numerous proposed interim decisions as well as some interim decisions for the pyrethroids. EPA plans to publish the remaining pyrethroid interim decisions in 2021

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EPA Registration Review Updates

Neonicotinoids

- * In February 2020, EPA published the Proposed Interim Decisions for the neonicotinoids acefamid, clothianidin, dinotefuran, imidacloprid, and thiamethoxam with proposed new measures reduce potential ecological risks, particularly to pollinators.
- * This included proposing language on residential labels noting that the products for use on ornamental plants are, "intended for use by professional applicators."
- * If this mitigation is included in the Interim Decision, we expect that this will reduce the likelihood of misapplication, overapplication, or spraying when pollinators are around, and therefore reduce risk to pollinators.
- * To address risks to aquatic invertebrates from applications around homes, EPA proposed to add language to labels:
 - * limiting band and perimeter treatments,
 - * defining the size of "spot" treatments,
 - * providing restrictions on applications to impervious horizontal surfaces except "spot" or crack and crevice treatments, and
 - * providing rainfall restriction statements.
- * The agency is also working with industry on developing and implementing stewardship and best management practices.
- * Approximately 190,000 comments were received on the proposed interim decisions
- * After reviewing public input, the agency anticipates issuing Interim Decisions in 2021.

EPA COVID-19 Response

Activated Emerging Viral Pathogens Guidance

- In January 2020, EPA activated—**for the first time ever**—its Emerging Viral Pathogens Guidance for Antimicrobial Pesticides
- Under this guidance, EPA allows manufacturers to provide the agency with data, even in advance of an outbreak, to show their products are effective against harder-to-kill viruses
- Once approved, these companies can make non-labeling marketing claims for use against the novel coronavirus



COVID-19 Response

- » Developed "List N" which now includes over **500 products** including **56** products with SARS-CoV-2 claims
- » List N is updated on a weekly basis
- » List N is searchable and sortable, comes with helpful tips on how to use disinfectants properly, and features frequently asked questions to ensure correct product usage
 - » **viewed 20 million times**
- » Created a mobile friendly app to allow consumers to easily find products approved by EPA for COVID-19 disinfection

List N: Disinfectants for Use Against SARS-CoV-2

All products on this list meet EPA's criteria for use against SARS-CoV-2, the virus that causes COVID-19.

Finding a Product

To find a product, enter the **first two sets** of its **EPA registration number** into the search bar below. You can find this number by looking for the EPA Reg. No. on the product label.

For example, if EPA Reg. No. 12345-12 is on List N, you can buy EPA Reg. No. 12345-12-1267 and know you're getting an equivalent product.

Search by EPA registration number

View List N's information in our new tool

<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>

List N Tool: COVID-19 Disinfectants

<input type="text"/>	Enter only the first two parts of the registration number (ex. 1234-12)
<input type="text"/>	
<input type="text"/>	
<input type="text"/>	
<input type="text"/>	
<input type="text"/>	



COVID-19 Response

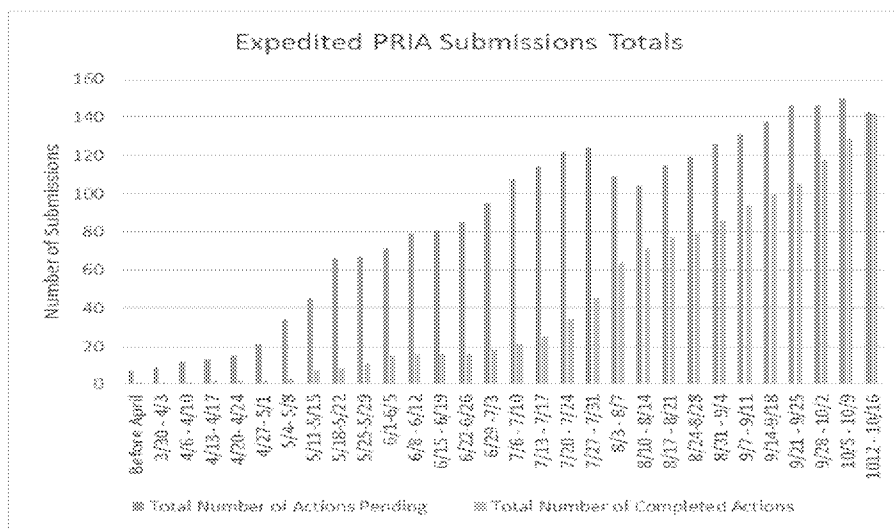
Expedited Registration

- EPA has also expedited several review processes for new and existing products intended for use against SARS-CoV-2
- In March, EPA announced that it would expedite the review process for products that were eligible for emerging viral pathogen claims without requiring the review of new data.
- In May, EPA expanded its expedited review program to include new products as well as amendments to existing product labels that require the review of new efficacy data.
- In July, EPA began to expedite applications to add directions for use with electrostatic sprayers to products intended to kill SARS-CoV-2

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Expedited AD PRIA Submissions





COVID-19 Response

Supply Chain Flexibilities

- In Spring 2020, EPA created flexibilities for manufacturers by temporarily allowing registrants to notify EPA of certain formulation and manufacturing facility changes and immediately release the product for sale without waiting for EPA approval
- For certain active and inert ingredients, companies are able to switch suppliers without waiting for EPA approval



COVID-19 Response

New Data Development

- EPA released an updated draft testing protocol for evaluating a copper surface's ability to kill bacteria and a draft protocol for evaluating the efficacy of antimicrobial surface coatings
- In August, EPA issued an emergency exemption to the state of Texas to allow American Airlines and Total Orthopedics Sports & Spine to use SurfaceWise2
 - manufactured by Allied BioScience, as a surface coating that inactivates viruses and bacteria within two hours of application and continues to work against them for up to seven days

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COVID-19 Response

New Data Development

- Developed guidance/test methods to add residual efficacy claims to products to be used against SARS-CoV-2
- Developed guidance for registrants to add electrostatic spray directions for products that qualify for List N
- Working aggressively with many companies of novel disinfectant technologies to work through our approval process
- These actions have provided the regulated community with guidance to generate data needed to register products that are effective against SARS –CoV-2 and increase the number of available products to quickly respond to the needs created by the COVID-19 public health emergency

EPA COVID-19 Response

Guidance on Pesticide Safety Training and Applicator Certification Programs

- EPA issued guidance to inform employers of flexibilities available under the Worker Protection Standard to allow continued protection for employees and agricultural production
- We issued temporary guidance that outlines approaches to address the unavailability of required respiratory protection and respiratory fit testing for agricultural pesticide handlers
- We also issued temporary guidance to provide flexibilities that meet both the needs of applicators and the requirements of the Certification of Pesticide Applicators rule

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EPA COVID-19 Laboratory Work

- **SARS CoV2**

- Completed formulation and efficacy testing of over 25 antimicrobial selected chemistries and formulations from List N against human coronavirus, along with several CDC-recommended treatment/cleaning procedures (70% ethanol, hypochlorite, etc)

- Analyzed the composition of approximately 20 suspicious disinfectant products and vendors, including imports, related to COVID-19 claims in support of EPA's Criminal Investigation Division

- Residual Method: developed a method for testing residual efficacy of surface coating materials claiming long-term disinfection

- **SARS CoV2** - Prepared Biosafety Level 3 laboratory, the only such EPA laboratory that exists, and staff to conduct efficacy testing against the SARS CoV2 virus

- Tested using surrogate coronavirus

- Obtained specialized PPE

- Transitioning to direct work on SARS CoV2 in 2021



Biotechnology Highlights

- Completed an EUP decision on genetically engineered mosquitoes (Oxitec OX5034) in Florida and Texas
- Prepared and forwarded to OMB the updated, draft Biostimulant Guidance
- Launched phase 1 of a Federal Outreach Project on Agricultural Biotechnology – FDA, USDA, EPA initiative to provide consumer outreach and education of agricultural biotechnology

EPA Endangered Species Highlights

- Released 3 new methodologies to improve drinking water assessments
- Released revised methods to conduct Biological Evaluations (BEs) under ESA
- Released draft BEs on methomyl and carbaryl
 - Hosted public webinar on the draft BEs for methomyl and carbaryl
- Submitted 2nd ESA report to Congress, highlighting the progress achieved in creating a more efficient and effective review process of pesticide impacts under ESA
- Released final avian waiver guidance and clarification guidance regarding acceptance of fish bioconcentration studies

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Work Supporting the Pollinator Initiative

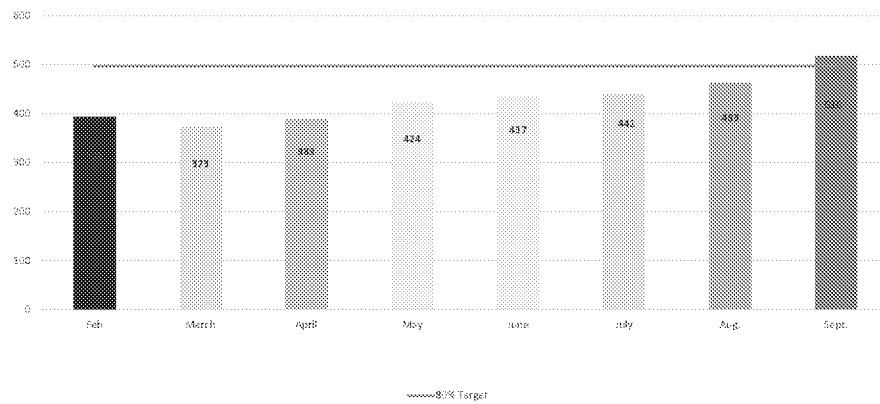
- Made significant strides in several areas that support the Administrator's Pollinator Initiative:
 - Co-hosted with USDA the Pollinator State of Science Workshop webinar
 - Hosted webinar, Agricultural Stewardship and Best Management Practices to Reduce Pollinator Risk
 - Conducted a series of 5 Pollinator-focused public webinars, including 2 on the design of honey-bee studies and the bee risk assessment framework
 - Established the first ever EPA Pollinator Week, joining our Federal partners with similar initiatives at the Department of Agriculture and the Department of the Interior

EPA Certification Plan - Review and Approval

- Finalized the Certification of Pesticide Applicators Rule to create stronger standards for people who apply restricted use pesticides
- All states, territories, tribes and federal agencies with certification programs were required to submit new or revised plans to EPA by March 4, 2020, that address the 2017 Certification of Pesticide Applicators Rule revisions (40 CFR Part 171)

EPA ELMS Deployment

FY 2020 OPP ELMS Deployment By Month



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EPA FY20 OPP Bowling Chart Results

Metric ID	Performance Metric Title	Custom Field	JOP	Target Direction		YTD
Breakthrough Metrics						
B01.OCSPP	Average number of days to complete PRIA decisions for new	N (mo) = 3; N (YTD) = 15	09/30/17 655	Decreasing	Target	619
					Actual	576
B02.OCSPP	Number of FIFRA decisions completed through pesticides		10/01/16 239	Increasing	Target	493
					Actual	481
Operational / Sustainment Metrics						
S01.OCSPP	Percentage of decisions (registration actions) completed	46 late out of 2385	10/01/16 94.0%	Increasing	Target	99.0%
					Actual	98.1%
S02.OCSPP	Average number of days exceeding the PRIA decision timeframes for	N (mo) = 2; N (YTD) = 14	09/30/17 316	Decreasing	Target	272
					Actual	353
S03.OCSPP	Percentage of pending new active ingredients for which PRIA due	=15/53	09/30/19 32.6%	Decreasing	Target	-
					Actual	28.3%
S04.OCSPP	Number of FIFRA registration review draft risk assessments		10/01/16 351	Increasing	Target	629
					Actual	646

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Thank you